

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appl. No. : 10/021,622
Applicant(s) : Paul F. Laeseke et al.
Filed : December 12, 2001
Title : Cauterizing Biopsy System
TC/A.U. : 3736
Examiner : Charles A. Marmor, II
Docket No.: : 1512.211

APPELLANT'S SECOND REVISED BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On or about November 17, 2005, Appellant appealed from the Final Rejection of claims 5-8 and 10. An Appeal Brief was submitted on January 17, 2006. On May 17, 2007 the Appellant received a Notification of Non-Compliant Appeal Brief indicating that statement of the status of the amendments was not provided nor a concise explanation of the subject matter of the claims in appeal. An Appellants' Revised Brief on Appeal was submitted June 14, 2007. On July 18, 2007 the appellant received a second Notification of Non-Compliance Appeal Brief indicating that the claims on appeal were not properly identify. Accordingly the appellant now submits this Second Revised Appeal Brief indicating that claims 5-8 and 10 are currently in appeal.

I. REAL PARTY IN INTEREST

The present application is assigned to the Wisconsin Alumni Research Foundation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 5 – 8 and 10 are currently pending in the subject patent application and stand finally rejected. Claims 1 – 4, 9, and 11 – 20 have been withdrawn from consideration. Claims 5-8 and 10 are currently on appeal.

IV. STATUS OF AMENDMENTS

In response to a final office action, an amendment was filed on July 18, 2005. In an advisory action dated October 14, 2005, the amendments were denied entry as raising new issues. Accordingly the claims have reverted to their status as all of the date of the final rejection all of May 17, 2005.

V. SUMMARY OF THE INVENTION

The citations in the following section refer to paragraph numbers of the published application.

The primary risk associated with biopsy of organs such as the liver is bleeding after the removal of the needle from the patient. Although bleeding occurs in a small number of patients, complications arising from the bleeding are severe and can lead to death. A secondary risk of biopsy procedures is the risk of the biopsy needle “seeding” cancer cells into other tissues and the bloodstream as the needle is withdrawn, resulting in the highly undesirable spread of cancer cells. It is extremely important when performing a biopsy in an organ, therefore, both to limit bleeding and to limit spread of cells to surrounding tissue, such that a biopsy can be reliably used

to cure the underlying problem rather than to exacerbate it. *Specification: paragraphs [0005]; [0008].*

The invention is a biopsy needle assembly (10) including a shaft sized and dimensioned for insertion percutaneously through the skin and tissue (34) of a patient and having a stylet (58) with an electrically conductive surface that is adapted to be exposed to tissue (34). A radio frequency electrical source (50) is coupled to the conductive surface and can be selectively activated to cauterize the tissue in the insertion path (56). The biopsy needle (36), includes a sampling means for removal of a tissue sample (40), and inter-fits with and is guided by the introducer shaft (12). The biopsy needle samples the tissue (34), and is guided through the shaft (12) to remove the sample (42). After the sample is removed, the cauterizing power source is energized (50), and the insertion path (56) is cauterized as the shaft is removed from the testing site. *Specification: paragraphs [0027]-[0029]; [0033]-[0039].*

The invention, therefore, provides a biopsy needle assembly (10) that includes a means for cauterizing the insertion path (56) to limit the primary risk associated with biopsy procedures of organs, specifically bleeding. In addition, the assembly provides an introducer shaft that allows a biopsy sample to be removed before cauterization preventing heat damage to the sample (42) and also limiting the possibility of “seeding” of cells. Cauterizing the path (54) after the sampling reduces the possibility of “seeding” as the introducer shaft itself is removed. The present invention, therefore, provides a substantial and important improvement over prior art biopsy devices, and substantially decreases the possibility of detrimental effects of biopsy procedures. *Specification: paragraphs [0037]-[0038].*

Claim 5 is an independent apparatus claim that recites a biopsy needle assembly comprising an introducer shaft (12) sized for percutaneous insertion into a patient along an

insertion path (56) to locate a conductive surface (58) at the second end (20) at a biopsy site (34). A cauterizing electrical source is connected to the second end (22) which communicates with tissue (34) at the conductive surface (58) by means of insulating conductor (18) to heat that tissue (34). A biopsy needle (36) interfits with the introducer shaft (12) and is guided thereby. The biopsy needle includes a sampling means (40) for removal of a tissue sample (42) before cauterization of the insertion path (56) using the electrically conductive surface (14).

Specification: paragraphs [0027]-[0040].

Claim 6 is an apparatus claim dependent on claim 1, which recites that the electrically conductive stylet (58) has a rounded tip. *Specification: paragraphs 38-40.*

Claim 7 is an apparatus claim dependent on claim 1, which recites that the introducer shaft (12) is a hollow tube (14) having an outer conductive covering (30) and wherein the insulated conductor is provided by a portion of the conductive stylet (58) fitting within the hollow tube (14). *Specification: paragraphs [0038]-[0040].*

Claim 8 is an apparatus claim dependent on claim 5, which recites the insulating covering (63) over a portion of the shaft of the conductive stylet to provide the insulated conductor.

Specification: paragraphs 38-40.

Claim 10 is an independent claim including all of the elements of claim 1 except for the stylet and instead reciting a temperature sensor (60) positioned at the electrically conductive surface. *Specification: paragraph 40.*

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Is claim 5 anticipated by Roberts, U.S. Patent 6,261,242, under 35 U.S.C. §102(e)?

B. Are claims 5 – 8 and 10 unpatentable over Roberts in view of Lennox, U.S. Patent 5,122,137?

VII. ARGUMENT

A. Is claim 5 anticipated by Roberts, U.S. Patent 6,261,242, under 35 U.S.C.

§102(e)?

a. Rejection under 35 U.S.C. §102(e). Claim 5 recites a biopsy needle assembly. The needle assembly includes an introducer shaft and a biopsy needle. The introducer shaft is sized for percutaneous insertion into a patient along an insertion path to a biopsy site. The end to be located at the biopsy site includes an electrically conductive stylet that is adapted to be exposed to tissue, and which communicates with a radio frequency cauterizing electrical source. The biopsy needle interfits with and is guided by the introducer shaft, and includes a biopsy needle having a sampling means for removal of tissue. A large area electrode completes a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface allowing cauterization of the insertion path as the biopsy needle is withdrawn.

Referring to paragraph [0004] of the application as published, the stylet is discussed as a “sharp rod”. Referring also to paragraph [0032], the stylet is again described as “rod-shaped ... having a sharpened end”.

The Examiner, referring to Figs. 4a through 4c, asserts that Roberts teaches a biopsy sampler including an introducer shaft 50 having an electrically conductive surface 22 on a conductive stylet. In the comments associated with the advisory action, the Examiner cites two definitions for percutaneous: “passed, done, or effected through the skin” and “effected or performed through the skin”. Based on these definitions, the Examiner asserts that “percutaneous” could mean “through a port or incision in the skin of the abdominal region”, and suggests that the device disclosed by Roberts could be inserted through such an incision. The

Examiner further asserts that a stylet is merely a “surgical probe”, and therefore that elements 12 and 134 of the Roberts reference are each “stylets”.

b. The Roberts Reference.

Referring to Figs. 1 – 3, Roberts discloses a biopsy sampler 10 that includes two basic parts: a cauterizing sheath 12 and a resecting device 14. The resecting device 14 includes a forceps 30 for taking a biopsy sample. Electrodes 22a and 22b are provided on the sheath 12, and are connected to an RF generator providing an energy source for cauterizing tissue with an electrode.

Referring to Figs. 4a through 4c and the associated description at column 5, line 51 through column 6, line 36, use of the biopsy sampler 10 is described. The biopsy sampler is shown inserted into an endoscope 50, which is inserted through a pre-existing body cavity in the patient, here specifically a colon 48. After a sample is retrieved with forceps 30, the electrodes cauterize the biopsy site and the entire biopsy assembly 10 is then retracted through or with the endoscope.

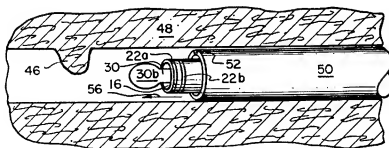


FIG. 4b

c. The Roberts Reference does not Anticipate Claim 5.

Based on the discussion above, it is clear that there are a number of substantial differences between the invention as recited in claim 5 and the biopsy sampler disclosed in the Roberts reference.

First, Roberts does not teach a "biopsy needle assembly". There is simply no structure in Rogers that would be considered a biopsy needle as would be understood in the art. A biopsy needle is a specific piece of equipment that may pierce a patient's tissue to sample a tumor buried therein. To call Roger's forceps 30, sheath 12, or endoscope 58 a biopsy needle system defies the plain and ordinary meaning of these words, the understanding of those of ordinary skill in the art, and the clear teaching of the specification.

Second, the element equated by the Examiner with the claimed "introducer shaft...for percutaneous insertion" is an endoscope 50 particularly designed to be introduced into body cavities without incisions or the like. The intentionally compliant and flexible endoscope does not provide a "shaft sized for percutaneous insertion"--it is clearly too large and too blunt and too flexible. A physician would never attempt to insert an endoscope through a patient's skin.

Even if one were to assume that the endoscope of Rogers were an "introducer shaft", which it is clearly not, the conductive surface, electrodes 22a and 22b are not at a first end of the endoscope 50, as required by the claim, but on a sheath 12 fitting within the endoscope. The sheath 12 also does not qualify as an introducer shaft for the same reasons described above: it is too large, implicitly too flexible, and too blunt.

Third, Roberts fails to teach the biopsy needle itself. As noted above, a biopsy needle is a well understood term of art, and a person of ordinary skill in the art or reading the plain and ordinary words of the claim would never mistake forceps for a biopsy needle.

Fourth, Rogers fails to teach any element equivalent to a stylet. A “stylet” as defined by Webster’s New Universal Unabridged Dictionary, Barnes & Noble, 1996, is “a stiletto or dagger” or “any similar sharp pointed instrument”, that is, a device that might pierce tissue. As discussed in the specification, a stylet is a component that includes a functionally tapered end. Whether relying on a dictionary meaning or on a meaning construed from the specification, therefore, the term “stylet” must mean an elongate object that may pierce tissue. The Examiner has not identified an element of Roberts that could fairly be called a stylet.

Roberts teaches away from the present invention by teaching a biopsy assembly 10 and endoscope 50 that are not inserted percutaneously, through the skin, but into a pre-existing body cavity. The problems of bleeding along the path of the insertion outside of the biopsy location or the seeding of tumor cells is not taught or suggested. The Examiner’s assertion that percutaneous could mean “through a port or incision in the abdomen”, defies the plain and ordinary meaning of this word and the clear teaching of the specification. As commonly understood, percutaneous refers to a medical procedure where access to tissue is done via needle-puncture of the skin. Under the Examiner’s definition, open heart surgery would be considered “percutaneous”; an extreme and strained interpretation of words that are not, in fact, ambiguous to those of ordinary skill in the art.

Since the endoscope 50 and biopsy sampler in the Roberts reference are inserted through the colon 48, there is, moreover, no insertion path into the body to be cauterized. Moreover, it would be highly undesirable to cauterize the insertion path of an endoscope threaded through a colon as it would destroy the colon’s functional wall.

Roberts, therefore, does not recite all of the elements of claim 5, and cannot anticipate claim 5. The device disclosed by Roberts, moreover, does not provide the advantages of the

present invention, and particularly cannot be used to limit the seeding of cancer cells when inserting a probe percutaneously, as discussed above. In view of these facts, the Appellants respectfully request that the rejection of claim 5 under 35 U.S.C. §102(e) be overturned.

B. Are claims 5 – 8 and 10 unpatentable over Roberts in view of Lennox, U.S.

Patent 5,122,137?

a. Rejection under 35 U.S.C. §103. Claims 5 – 8 and 10 were also rejected under 35 U.S.C. §103 as unpatentable over Roberts in combination with Lennox.

Independent claim 5 is discussed above. Independent claim 10 recites a biopsy needle assembly including an introducer shaft sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site. A first end of the shaft includes an electrically conductive surface adapted to be exposed to tissue, and connected with a radio frequency cauterizing electrical source. A biopsy needle interfits with and is guided by the introducer shaft, and includes a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface. A temperature sensor is positioned at the electrically conductive surface.

Here, the Examiner asserts that Roberts teaches an introducer shaft 12 including an electrically conductive surface 22, a biopsy needle 14 including a sampling means 30, and a stylet interfitted with the shaft, referencing Fig. 8b. Lennox is cited for disclosing a conductive stylet with a rounded tip (claim 6) and a temperature sensor disposed on the electrically conductive surface (claim 10).

The Examiner further asserts that it would be obvious to “withdraw a biopsy needle from an introducer shaft similar to that of Roberts after a biopsy sample is taken and to then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and

coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage, and leakage, while providing an indirect means of measuring and controlling the temperature”. The Examiner, however, cites no passage in one thing when either reference to support this suggestion.

b. The Roberts and Lennox References. As discussed above, Roberts discloses a biopsy sampler assembly 10 that is inserted into a colon 48 through an endoscope 50. The biopsy sampler 10 includes an outer sheath 12 having electrodes 22a and 22b provided on an outer surface, and a resecting device 14, provided inside of the sheath 12. In use, the biopsy sampler is inserted into the endoscope 50. After a sample is retrieved with forceps 30, the electrodes cauterize the biopsy site and the entire biopsy assembly 10 is then retracted without further cauterization either through the endoscope or with the endoscope.

Lennox discloses a temperature-controlled RF coagulation device including a sensor for modulating the RF voltage to adjust temperature. The RF coagulation device and sensor are shown incorporated in a number of different types of medical devices including an RF probe, a needle probe, a catheter, a guidewire probe, and a forceps probe.

c. The Combination of Roberts and Lennox Does Not Render Claims 5 – 8 and 10 Obvious.

As noted above, the Examiner asserts that it would have been obvious at the time the invention was made to “withdraw a biopsy needle from an introducer shaft similar to that of Roberts after a biopsy sample is taken and then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage, and leakage, while providing an indirect means of measuring and controlling the temperature”.

Neither of the cited references, however, suggests such an operation and the Examiner has simply presupposed the present invention.

As described above, Roberts discloses a biopsy assembly 10 that is inserted through a pre-existing cavity in the patient, and through an endoscope. Roberts, therefore, teaches away from any need to cauterize an insertion path.

Roberts, by inserting the biopsy assembly into the colon and through an endoscope, further teaches away from the need for an element to pierce the skin and the creation of an insertion path that would require cauterization. As a result, it is not necessary, and indeed not desirable, to include an element to pierce the skin for insertion, and the only cauterization required, and discussed is cauterization of the biopsy site.

Roberts, moreover, already includes an electrode for providing cauterization of the biopsy site. There is, therefore, no motivation to modify Roberts to insert another unnecessary electrode device as suggested by the Examiner. In fact, in the background section, Roberts discusses the disadvantages of using separate biopsy and cauterizing elements (see column 1, lines 19 – 32). Rather than suggesting the construction discussed by the Examiner, therefore, Roberts teaches away from such a construction.

Lennox discloses a method for treating tissue using an RF power source, but does not discuss any particular method for performing a biopsy. The only equipment shown that is suitable for use in a biopsy procedure is the forceps of Figs. 7 and 8. These forceps each include RF electrodes embedded in the tips of the forceps to provide coagulation or cauterization. Therefore, it is clear that the forceps are constructed to include the elements necessary to cauterize tissue. Lennox, therefore, does not suggest inserting a biopsy tool, removing the

biopsy tool, and replacing the biopsy tool with a cauterizing tool. Rather, Lennox suggests removing and cauterizing tissue with a single tool.

Neither of the cited references, moreover, discusses cauterization of an insertion path to avoid tumor seeding or to minimize bleeding. These elements are only discussed in the Appellants' application. Clearly, the cited motivation to combine Roberts and Lennox, therefore, is not found within either of the cited references, but impermissibly from within the Appellants' disclosure.

The cited references therefore fail to provide all of the elements of the rejected claims. Moreover, the cited references do not provide any suggestion or motivation to combine elements as suggested by the Examiner. It is therefore not obvious to combine the references as asserted in the Office Action, and the Appellants respectfully request that the rejection of claims 5 – 8 and 10 under 35 U.S.C. §103 be overturned.

VIII. CONCLUSION

Claim 5 stands rejected under 35 U.S.C. §102(e) as anticipated by Roberts. Claims 5 – 8 and 10 stand rejected under 35 U.S.C. §103 as unpatentable over Roberts in combination with Lennox.

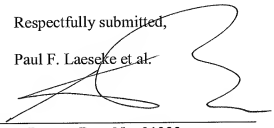
The rejection under 35 U.S.C. §102(e) is improper because Roberts fails to disclose all of the elements recited in claim 5. The rejection under 35 U.S.C. §103 is improper because the cited references fail to disclose all of the elements of the claims, and further because no proper

motivation to combine these references has been shown. Therefore, the Appellants respectfully request that the rejection of claims 5 – 8 and 10 be reversed.

Respectfully submitted,

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Dated: August 20, 2007

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CLAIMS APPENDIX

1-4. (Canceled)

5. (Previously Presented) A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

wherein the electrically conductive surface is a conductive stylet having a first end supported by the introducer shaft.

6. (Original) The biopsy needle assembly of claim 5 wherein the conductive stylet has a rounded tip.

7. (Previously Presented) The biopsy needle assembly of claim 5 wherein the introducer shaft is a hollow tube and wherein the insulated conductor is provided by a portion of the conductive stylet fitting within the hollow tube.

8. (Original) The biopsy needle assembly of claim 5 wherein a shaft portion of the conductive stylet includes an outer insulating covering to provide the insulated conductor.

9. (Canceled)

10. (Previously Presented) A biopsy needle assembly comprising:
an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

further including a temperature sensor positioned at the electrically conductive surface.

11-20. (Canceled)

EVIDENCE APPENDIX

No additional evidence is being presented.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.